Q&A SESSION WITH RAKESH DIXIT

RAKESH DIXIT, Vice President, R&D, **MedImmune**

In Aug 2006, Rakesh joined MedImmune, Inc. (an AstraZeneca Biologics company) as Senior Director (R&D) & Global Head of Biologics Safety Assessment, Experimental Pathology, and Laboratory Animal Medicine. In his current position as a Vice President of R&D, Rakesh is responsible for providing guidance on research and development of biological products; including nonclinical toxicology/safety support for all AstraZeneca-MedImmune biologics products, including monoclonal antibodies and vaccines. Rakesh has published more than 60 papers in renowned international journals and has given over 100 invited lectures/presentations/workshops in national and international meetings.

At our upcoming 3rd Annual Biosimilars & Biobetters Congress you will be delivering a presentation about the challenges and opportunities in developing best in class biosuperiors or biobetter biologics. What are the most important challenges the industry should be aware of?

The most important challenges are the clinical challenges of demonstrating superiority in the effectiveness (e.g. efficacy, safety, and dosing convenience) of the test biosuperior over the existing molecules in patients.

Identifying which products have significant potential for biosuperior development is not always straightforward. In your opinion, which key elements should biosimilar experts take into consideration during the process?

The development of biosuperiors requires significant investment in early discovery research to gain confidence in potential biosuperiority and then conducting clinical superiority trials. The high-risk biologics may not be appropriate for biosimilar development due to heightened safety risks and very lengthy trials.

What are the most interesting biosimilars and biobetters technologies that researchers should be excited about?

The potency enhancing, half-life extending, bispecific and antibody drug conjugate technologies offer some of the best ways to develop biosuperiors within the same therapeutic MOA areas. Additional technologies may include delivery technologies to enhance the convenience of dosing to patients.

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